REMARKS/ARGUMENTS

Reconsideration of this application and entry of the foregoing amendments are respectfully requested.

At the outset, the undersigned wishes to express appreciation to the Examiner for the telephonic interview of June 25, 2009. The Examiner's record adequately summarizes that interview, thus, no further comment is believed necessary.

The claims have been amended to define the invention with additional clarity. The above-noted revisions correspond to those discussed with the Examiner during the June 25, 2009 interview. The claims as presented are fully supported by an enabling disclosure.

Claims 2 and 3 have been cancelled without prejudice thereby mooting the Examiner's objection to those claims.

Claims 1-3 and 7-12 stand rejected under 35 USC 102(b) as allegedly being anticipated by Neurath et al (EP1564902A). These same claims also stand rejected under 35 USC 102(b) as allegedly being anticipated by Neurath et al (EP448126A) and Neurath et al (USP 4,847,080). Withdrawal of these rejections is submitted to be in order in view of the above-noted claim revisions and further in view of the comments that follow.

Claim 1 has been amended so as to be drawn to a method of determining whether an individual having HBV will respond to IFNα treatment. The method comprises obtaining a pre-treatment sample for the HBV infected individual and analyzing that sample for the presence or absence of anti-preS1 (94-117) antibodies. In accordance with the method, the presence of the antibodies indicates the individual will respond to IFNα treatment and the absence indicates the individual will not respond.

As pointed out previously, Neurath et al (EP1564902A), Neurath et al (EP448126A) and Neurath et al (US4,847,080) do not contain any teaching whatsoever regarding the prognostic or predictive value of anti-preS194-117 antibodies for the outcome of hepatitis B, nor do any of these documents disclose a correlation between the presence of preS1 (94-117) antibodies in an individual who has been diagnosed with an HBV infection and the responsiveness of that individual to IFNα treatment. In the absence of such teachings, neither Neurath et al (EP1564902A), Neurath et al (EP448126A) nor Neurath et al (US4,847,080) disclose the claimed method of determining whether or not an individual will respond to IFNα treatment. In the absence of any determination of the responsiveness of an individual to IFNα therapy from the presence or absence of preS1 (94-117) antibodies, instant claims 1 to 3 and 7 to 12 are novel over any one of Neurath et al (EP1564902A), Neurath et al (EP448126A) and Neurath et al (US4,847,080). Reconsideration of the rejections raised under 35 USC 102(b) is, therefore, requested.

Claims 4-6, 20 and 22 stand rejected under 35 USC 103(a) as allegedly being obvious over Neurath et al (EP1564902A), Neurath et al (EP448126A) or Neurath et al (US4,847,080), in view of Zavaglia et al. Withdrawal of the rejection is submitted to be in order in view of the above-noted claim revisions and for the reasons tat follow.

Neurath et al (EP1564902A), Neurath et al (EP448126A) and Neurath et al (US4,847,080) all teach peptides for use as HBV immunogens and vaccines, which comprise at least six consecutive amino acids encoded by the pre-S region of the env gene of HBV. Zavaglia et al teaches that interferon-α inhibits HBV replication in a minority of patients with chronic hepatitis B.

The combination of Neurath et al (EP1564902A), Neurath et al (EP448126A), Neurath et al (US4,847,080) and Zavaglia et al would have failed to teach or suggest any correlation between the presence of preS1 (94-117) antibodies and the responsiveness of an individual to IFNα therapy. In the absence of disclosure of this correlation, one of ordinary skill in the art would not have been motivated to determine the responsiveness of an individual to IFNα therapy from the presence of preS1 (94-117) antibodies. In the absence of any disclosure of determining responsiveness to IFNα therapy, the combination of Neurath et al (EP1564902A), Neurath et al (EP448126A), Neurath et al (US4, 847,080) and Zavaglia et al could not have suggested the claimed invention and reconsideration is requested.

This application is submitted to be in condition for allowance and a Notice to that effect is requested. Should the Examiner find any issues to remain outstanding, she is urged to contact the undersigned by phone prior to the issuance of any further Action.

Respectfully submitted,

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